

USCI Division
C.R. Bard, Inc.
Clinical and Regulatory Affairs
1200 Technology Park Drive
P.O. Box 7025
Billerica, MA 01821
(508) 667-1300
FAX: (508) 670-4326

AUG 12 1996

K960445



SECTION 6.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

As required under Section 12, part (a)(i)(3A) of the Safe Medical Device Act of 1990, an adequate summary of any information respecting safety and effectiveness follows.

6.1 General Information

◆ **Name and Address of Submitter:**

USCI Division of C.R. Bard, Inc.
1200 Technology Park Drive
Billerica, MA 01821

◆ **Contact:**

Robert T. Miragliuolo
Director, Regulatory Affairs

◆ **Date of Summary:**

January 31, 1996

◆ **Name of Device:**

USCI® Input™ Tuohy-Borst Locking Device

◆ **Common/Usual Name of Device:**

Angiographic/Angioplasty Accessory Device

◆ **Device Classification:**

Cardiopulmonary Bypass Adapter, Stopcock, Manifold or Fitting

◆ **Predicate Device:**

USCI® Disposable Y-Connector w/Modified Tuohy-Borst Adapter

◆ **Description and Intended Use of Device:**

The USCI® Input™ Tuohy-Borst Locking Device (hereinafter referred to as the Input Lock) is comprised of a single channel (body) which at its distal segment connects to the introducer sheath hub and ends proximally with a threaded segment containing an internally seated gland. Attached to this threaded proximal segment is an end cap which when thread tightened compresses the gland and secures the indwelling catheter.

The Input Lock functions as a removable, adjustable valve indicated as an adjunctive measure to help secure a catheter to an introducer in order to reduce the risk of inadvertent movement.

6.2 Summary of Similarities and Differences

Please refer to Exhibit 6.2, on the following page, for a Table of the Similarities and Differences.

The Input Lock is new to the USCI line of accessory devices. It utilizes the "locking" design characteristic of the USCI® Disposable Y-Connector with Modified Tuohy-Borst Adapter (K890325, concurrence received March 15, 1989 and hereinafter referred to as the Disposable Y-Connector). Both devices consist of a body, and an end cap, both which differ in configuration, and a gland. The Disposable Y-Connector differs such that the body contains a distal fitting that rotates (with an internal O-ring for ease of rotating movement) and a washer side by side with the gland. The Disposable Y-Connector also contains a second proximal channel for connection to a manifold. The Input Lock is a less bulky device that attaches to the introducer sheath hub while the Disposable Y-Connector attaches to a catheter hub.

The two devices have the identical mechanism for reducing the risk of inadvertent catheter movement. When the end caps of both devices are thread tightened to the body, the I.D. of the internal gland constricts around the I.D. of the indwelling catheter.

The Disposable Y-Connector is indicated for PTA, PTCA pressure monitoring, dye infusion and flushing. However, the Instructions for Use (IFU) provided in the 510(k) Premarket Notification (K890325) indicate that this device has "... an adjustable gland adjusting to form a seal with or without a guide wire in place." The IFU contains two precautions "Do not collapse the lumen of the balloon dilatation catheter or impair free movement of the guide wire by adjusting the Tuohy-Borst adapter" (compression of the gland) "too tightly." and "Excessive tightening of the Tuohy-Borst adapter may inhibit the ability to monitor distal pressures, manipulate the steerable guide wire, or deflate the balloon."

The Input Lock functions as a removable, adjustable valve indicated as an adjunctive measure to help secure a catheter to a USCI Input Introducer in order to reduce the risk of inadvertent catheter movement.

Exhibit 6.2

Table of Similarities and Differences

<u>Component/ Characteristic</u>	<u>Input Lock</u>	<u>Disposable Y-Connector</u>
Body*	ABS**	Polycarbonate
End Cap	Nylon	Polycarbonate
Gland	Silicone	Silicone
Washer (side by side w/gland)	N/A	Teflon
"O" Ring (internal to distal fitting)	N/A	Silicone
Distal Fitting (of the body)	threaded & stationary	threaded & rotates
Distal Fitting	attaches to introducer sheath	attaches to catheter hub
Body Length (nominal)	1.0"	2.6"
Gasket I.D. (nominal)	.120"	.075"
Channel I.D. (nominal)	.110"	.125"

* The Input Lock body with distal fitting is one molded segment. The Disposable Y-Connector body and distal rotating fitting is comprised of three (3) parts: the molded Y-body , the O-ring and the molded rotating fitting which houses the O-ring.

** Acrylonitrile Butadiene Styrene